AUG 2 0 2001

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510(k) Summary of Safety and Effectiveness

July 31, 2001

Submitter

Welch Allyn Protocol, Inc.
8500 S.W. Creekside Place
Beaverton, OR 97008-7107
USA

Telephone: (503) 526-8500
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Contact: Mr. Donald M. Abbey, Vice President, Quality Systems

Device Name

Trade Name: Propaq 200 Series Monitors
Common Name: Cardiac Monitor
Classification Name: Cardiac Monitor (Reference, 21CFR870.2300, April 1, 1999). The Propaq Monitors also contains a Pulse Oximetry (SpO_2) channel (Reference, 21CFR870.2700, April 1, 1999).
Classification: Class II

Predicate Device

The predicate device for the Propaq 200 Series Monitors is the Propaq 200 Series cleared for market under 510(k) submissions K945071 and K951246, except for the improved SpO_2 Channel. The predicate device for the improved SpO_2 Channel in the Propaq 200 Series is the Nellcor model N-395 Pulse Oximeter cleared for market under 510(k) submissions K951246 and K993637.

Device Description

The Propaq 200 Series monitors are small, light weight, portable, multi-parameter patient monitors equipped with either a monochrome or color display. The monitors provide real time monitoring and display of ECG, respiration, invasive blood pressure, noninvasive blood pressure, temperature, CO_2 and SpO_2. Rechargeable batteries power the monitors. The Propaq 200 Series monitors can communicate with Welch Allyn Protocol's Acuity® central station through a local area network. The communication link is bi-directional, providing monitoring at the Acuity central station and remote control of the Propaq from the Acuity central station.

Indications for Use

The Propaq 200 Series monitors are intended to be used by skilled clinicians for multiparameter vital signs monitoring of neonatal, pediatric, and adult patients in health care facility bedside applications; as well as for intrafacility and interfacility transport.

Technological Comparison to the Predicate Device
The Protocol 200 Series monitor is the same as the Propaq 200 Series Monitors cleared for market under 510(k) submission numbers K945071 and K951246. The improved SpO_2 channel in the Propaq 200 Series is a replacement for the SpO_2 channel currently in the Propaq 200 Series monitors. Nellcor Puritan Bennett manufactures the SpO_2 Channel currently in the Propaq 200 series. The improved SpO_2 channel is also manufactured Nellcor Puritan Bennett. The improved SpO_2 channel is substantially equivalent to the SpO_2 channel in the Nellcor model N-395 Pulse Oximeter. The Nellcor model N-395 was cleared for market under 510(k) submissions K991823 and K993637.

Summary of Performance Testing
The Propaq 200 Series monitors and associated accessories have been tested and found to comply with the recognized national and international, performance, safety, and electromagnetic compatibility standards for medical devices and product specifications listed in the Propaq labeling.

A risk analysis, identifying potential hazards and documenting mitigation of the hazards, has been developed and verified/validated as part of Welch Allyn Protocol's product development procedures. Welch Allyn Protocol's Quality System conforms to 21CFR820 and is certified by TUV Product Service to ISO 9001 and EN46001.

Conclusions
As stated above, Protocol's conclusion is that the Propaq 200 Series monitors are safe, effective, comply with the appropriate medical device standards, and equivalent to the Propaq 200 series currently on the market.

This *510(k) Summary of Safety and Effectiveness* may be copied and submitted to interested parties as required by 21CFR807.92.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 0 2001

Mr. Donald M. Abbey
Vice President, Quality System
Welch Allyn Protocol, Inc.
8500 S.W. Creekside Place
Beaverton, OR 97008-7107

Re: K012451
Trade Name: Propaq Encore Models 202, 204, 206; Propaq CS Models 242, 244, 246
Regulation Number: 21 CFR 870.2300
Regulatory Class: II (two)
Product Code: 74 DRT
Dated: July 31, 2001
Received: August 1, 2001

Dear Mr. Abbey:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4645. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

Applicant:
Welch Allyn Protocol. Inc.
Beaverton, OR 97008-7107
USA

Telephone: (503) 526-8500
Fax: (503) 526-4245

510(k) Number: K012451

Device Name: Propaq 200 Series Monitors

Indications for Use:
The Propaq 200 Series monitors are intended to be used by skilled clinicians for multiparameter vital signs monitoring of neonatal, pediatric, and adult patients in health care facility bedside applications; as well as for intrafacility and interfacility transport.

(Please do not write below this line – continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___X___ OR Over-The Counter _____

Division of Cardiovascular & Respiratory Devices
510(k) Number K012451